



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB 17 1999

5 3 0 6 '99 FEB 23 P1:48

Mr. R. Vannaken
VP Sales and Marketing
Far East Summit
P.O. Box 2486
Culver City, California

Dear Mr. Vannaken:

This is in response to your letter of January 14, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Far East Summit is marketing a product named "PMS Solution" and that it bears a label claim that it is intended to "alleviate periodic discomfort."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product, which includes the product name "PMS Solution" suggest that this product is intended to treat, prevent, cure, or mitigate a disease, namely premenstrual syndrome (i.e., PMS). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

975-0163

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Page 2 --Mr. R. Vannaken

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, File)

HFS-450 (r/f, File)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

HFV-228 (SBenz)

HFV-232 (ABrown)

GCF-1 (Dorsey)

f/t:HFS-456:rjm:2/16/99:docname:63601.adv:disc35



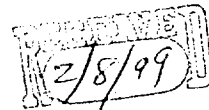
FAR EAST
SUMMIT

Quality Chinese
Herbal Products

1/14/99

Department of Health and Human Services

Washington D.C.



Dear Secretary,

My company will soon introduce a new product into the natural supplement marketplace.

In accordance with DSHEA Section 6, please accept this notification of statements, which appear on the label for PMS Solution premenstrual formula:

"This formulation helps to balance a woman's monthly cycle and alleviate periodic discomfort."

Dr. Lin Cheng Tan, M.D. (China), O.M.D., L.Ac., developed DR. LIN'S LIFESTYLE SOLUTIONS specifically to meet the needs of women. Through years of research in her clinical practice, Dr. Lin created these safe and highly effective herbal preparations which combine modern formula logic with the wisdom of Traditional Chinese Medicine (TCM).

PMS SOLUTION Premenstrual Formula™ is a modern formula that incorporates traditional herbs used by women for centuries to support a healthy gynecological system. When used as directed, this formula helps to balance a woman's monthly cycle and alleviate periodic discomfort.*

*This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

LIFESTYLE SOLUTIONS



PMS SOLUTION
premenstrual formula

CHINESE HERBAL
SUPPLEMENT

60 Capsules • 500mg Each

Ingredients: White Peony root, Gardenia fruit, Prunella spike, Albizzia bark, Bupleurum root, Dang Gui root, Mouton root bark, Ligusticum wallichii root, and Cyperus rhizome. 100% concentrated extract - No fillers.

Suggested Use: 2 capsules 3 times daily. Take for 2 weeks prior to menstruation.

Do not use this product if pregnant/lactating unless directed by a health care practitioner. KEEP OUT OF REACH OF CHILDREN.



Far East Summit, LLC
Santa Monica, CA 90404



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Thank you,

R. Vannaken

R. Vannaken
VP Sales and Marketing
Far East Summit

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